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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,164	11/26/2003	Stephan R. Targan	67789-711	8299

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,164	TARGAN ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26 and 29-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-26 and 29-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 07/06/2007 is acknowledged.

2. Claims 25-26 and 29-36 are pending.

3. Claims 25-26 and 29-36 are currently under consideration as they read on a method of determining a risk of having or developing a clinical subtype of Crohn's disease characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery in a subject having Crohn's disease, comprising determining the presence or absence of three markers in the subject, said three markers being IgA anti-I2 antibodies, anti-Saccharomyces cerevisiae antibodies (ASCA), and IgA anti-OmpC antibodies.

4. In view of the amendments filed on 07/06/2007, only the following rejections are maintained.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 25-26 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Targan et al. (PTO-892, Reference U) in view of Vasiliauskas et al. (Reference 30, IDS filed on 11/03/2004) and Landers et al. (Reference 17, IDS filed on 11/03/2004) for the same reasons as set forth in the Office Action mailed on 01/29/2007.

Applicant's arguments have been fully considered, but are not found persuasive.

Applicant argues in the response and declaration of Stephen Targan filed on 07/06/2007 that Targan et al. is not available as prior art under 102(a) and is thus not citable as prior art under 103(a). In the declaration, Stephen Targan states that Drs. Landers, Steinhart, Feagan and Greenberg are co-authors of Targan et al. (PTO-892 mailed on 01/29/2007, Reference U), but are not co-inventors of the subject matter of the instant application. Further Targan states that the work described Targan et al. only relates to his inventive contribution and not tot he contributions of his co-inventors.

It is the Examiner's position that the argument and declaration of Stephen Targan are insufficient to overcome the instant rejection under 103(a) because the Targan et al. reference is available as prior art under 102(b). The effective priority for the instant claims is the filing date of the instant application because there is insufficient support in the 10/413,501 application priority document's specification for the invention as claimed. Therefore, Targan et al. is

available as 102(b) prior art. In particular, there is insufficient support in the priority document for determining the magnitude of the markers and for determining the risk of having or developing a clinical subtype of Crohn's disease based on measuring anti-I2 antibodies, anti-Saccharomyces cerevisiae antibodies and IgA anti-OmpC antibodies. Therefore, the rejection stands for the same reasons as stated in the Office Action mailed on 01/29/2007.

Further, the declaration is insufficient to overcome the rejection because the reference is still considered to be by others. The declaration states that all of the other authors of the Targan et al. were working at the direction of Stephen Targan. Therefore, the declaration affectively states that Targan et al. has one inventor, Stephen Targan. However, the instant application has 6 inventors. Therefore, the reference is still by others because there is not one to one correspondence between the authorship and the declaration does not state the role of the other inventors on the instant application.

7. The following rejection is necessitated by the amendment filed on 07/06/2007.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 25-26 and 29-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The following phrases represent a departure from the specification and claims as originally filed:

A method of determining a risk of having or developing a clinical subtype of Crohn's disease characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery in a subject having Crohn's disease, comprising obtaining a sample from the subject, and **determining the magnitude of three markers in the subject, said three markers being IgA anti-12 antibodies, anti-Saccharomyces cerevisiae antibodies (ASCA), and IgA anti-OmpC antibodies, wherein a high magnitude of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a first risk of having or developing said clinical subtype of Crohn's disease, a high magnitude of exactly two of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a second risk of having or developing said clinical subtype of Crohn's disease, a high magnitude of exactly one of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a third risk of having or developing said clinical subtype of Crohn's disease, and the absence of a high magnitude of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a fourth risk of having or developing said clinical subtype of Crohn's disease, wherein the magnitude of each of said one or more markers is determined by contacting the sample with an antigen or fragment thereof specifically reactive with each of said one or more markers, and assaying for the magnitude of each of said one or more markers by detecting specific binding of said antigen or fragment thereof, and wherein said first risk is greater**

than said second risk, said second risk is greater than said third risk, and said third risk is greater than said fourth risk of claim 25;

A method of determining a risk of having or developing a clinical subtype of Crohn's disease characterized by the need for small bowel surgery in a subject having Crohn's disease, comprising obtaining a sample from the subject, and **determining the magnitude of three markers in the subject, said three markers being IgA anti-12 antibodies, anti-Saccharomyces cerevisiae antibodies (ASCA), and IgA anti-OmpC antibodies, wherein a high magnitude of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a first risk of having or developing said clinical subtype of Crohn's disease, a high magnitude the presence of exactly two of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a second risk of having or developing said clinical subtype of Crohn's disease, the a high magnitude of exactly one of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a third risk of having or developing said clinical subtype of Crohn's disease, and the absence of magnitude of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a fourth risk of having or developing said clinical subtype of Crohn's disease, wherein the magnitude of each of said one or more markers is determined by contacting the sample with an antigen or fragment thereof specifically reactive with each of said one or more markers, and assaying for the magnitude of each of said one or more markers by detecting specific binding of said antigen or fragment thereof, and wherein said first risk is greater than said second risk, said second risk is greater than said third risk, and said third risk is greater than said fourth risk** of claim 26;

A method of determining a risk of having or developing a clinical subtype of Crohn's disease characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery in a subject having Crohn's disease, comprising obtaining a sample from the subject, and **determining the magnitude of three markers in the subject, said three markers being IgA anti-12 antibodies, anti-Saccharomyces cerevisiae antibodies (ASCA), and IgA anti-OmpC**

antibodies, wherein the magnitude of each of said one or more markers is determined by contacting the sample with an antigen or fragment thereof specifically reactive with each of said one or more markers, and assaying for the magnitude of each of said one or more markers by detecting specific binding of said antigen or fragment thereof, wherein a greater magnitude of said three markers combined relative to levels found in individuals who do not have Crohn's disease indicates a greater risk of having or developing said clinical subtype characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery of claim 29;

The method according to claim 29, **wherein the step of determining the magnitude of three markers in the subject further comprises a step of performing quartile analysis of the magnitude of each marker** of claim 30;

The method according to claim 30, **wherein quartile analysis further comprises assigning scores based on the quartile into which a marker falls and then adding the scores to obtain a quartile sum score whereby a higher quartile sum score indicates a greater risk of having or developing said clinical subtype characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery** of claim 31;

A method of determining a risk of having or developing a clinical subtype of Crohn's disease characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery in a subject having Crohn's disease, comprising obtaining a sample from the subject, and **determining the magnitude of three markers in the sample in conjunction with one another, said three markers being IgA anti-12 antibodies, anti-Saccharomyces cerevisiae antibodies (ASCA), and IgA anti- OmpC antibodies, wherein a high magnitude of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a first risk of having or developing said clinical subtype of Crohn's disease, a high magnitude of exactly two of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a second risk of having or developing said clinical subtype of Crohn's disease, a high magnitude of exactly one of said three markers relative**

to levels found in individuals who do not have Crohn's disease indicates a third risk of having or developing said clinical subtype of Crohn's disease, and a low magnitude of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a fourth risk of having or developing said clinical subtype of Crohn's disease, wherein the magnitude of each of said one or more markers is determined by contacting the sample with an antigen or fragment thereof specifically reactive with each of said one or more markers, and assaying for the magnitude of each of said one or more markers by detecting specific binding of said antigen or fragment thereof, and wherein said first risk is greater than said second risk, said second risk is greater than said third risk, and said third risk is greater than said fourth risk of claim 32;

A method of determining a risk of having or developing a clinical subtype of Crohn's disease characterized by the need for small bowel surgery in a subject having Crohn's disease, comprising obtaining a sample from the subject, and **determining the magnitude of three markers in the sample in conjunction with one another, said three markers being IgA anti-12 antibodies, anti-Saccharomyces cerevisiae antibodies (ASCA), and IgA anti-OmpC antibodies, wherein a high magnitude of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a first risk of having or developing said clinical subtype of Crohn's disease, a high magnitude of exactly two of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a second risk of having or developing said clinical subtype of Crohn's disease, a high magnitude of exactly one of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a third risk of having or developing said clinical subtype of Crohn's disease, and a low magnitude of said three markers relative to levels found in individuals who do not have Crohn's disease indicates a fourth risk of having or developing said clinical subtype of Crohn's disease, wherein the magnitude of each of said one or more markers is determined by contacting the sample with an antigen or fragment thereof specifically reactive with each of said one or more markers, and assaying for the magnitude of each of said one or more markers by detecting specific binding of said antigen or fragment thereof, and wherein said first risk is greater than said second risk,**

said second risk is greater than said third risk, and said third risk is greater than said fourth risk of claim 33;

A method of determining a risk of having or developing a clinical subtype of Crohn's disease characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery in a subject having Crohn's disease, comprising obtaining a sample from the subject, and **determining the magnitude of three markers in the sample in conjunction with one another, said three markers being IgA anti-12 antibodies, anti-Saccharomyces cerevisiae antibodies (ASCA), and IgA anti- OmpC antibodies, wherein the magnitude of each of said one or more markers is determined by contacting the sample with an antigen or fragment thereof specifically reactive with each of said one or more markers, and assaying for the magnitude of each of said one or more markers by detecting specific binding of said antigen or fragment thereof, wherein a greater magnitude of said three markers combined relative to levels found in individuals who do not have Crohn's disease indicates a greater risk of having or developing said clinical subtype characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery** of claim 34;

The method according to claim 34, **wherein the step of determining the magnitude of three markers in the sample further comprises a step of performing quartile analysis of the magnitude of each marker** of claim 35; and

The method according to claim 35, **wherein quartile analysis further comprises assigning scores based on the quartile into which a marker falls and then adding the scores to obtain a quartile sum score whereby a higher quartile sum score indicates a greater risk of having or developing said clinical subtype characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery** of claim 36.

Applicant's amendment filed 07/06/2007 points to the specification at page 82, lines 10-27 for support for the newly added limitations as claimed in claims 25-26 and 29-36. However, the specification does not provide a clear support for the aforementioned claim limitations. In

particular, there is no support for the determination of anti-I2 antibodies, ASCA and OmpC together for the recited method. Further, there is no support for determining the magnitude of the markers. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed in the 10/413,501 application priority document.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937.

The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 12, 2007

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER